

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**THIS PAGE BLANK (USPTO)**

PCT

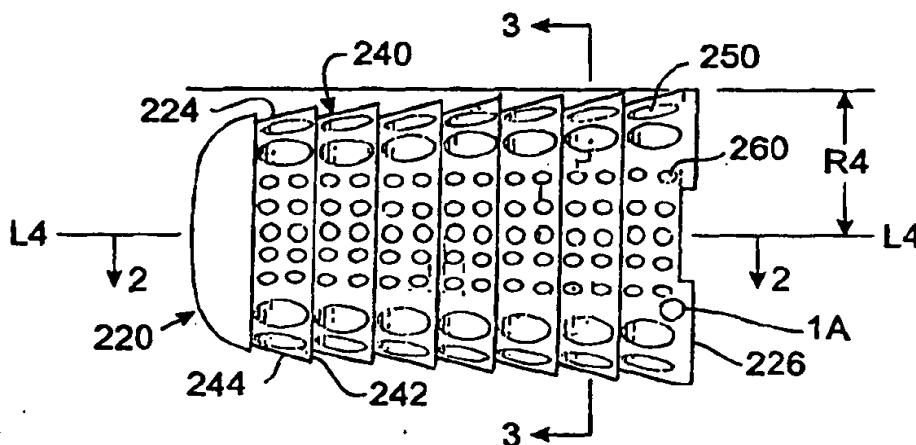
WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61F 5/04</b>		<b>A1</b>	(11) International Publication Number: <b>WO 96/40019</b>
			(43) International Publication Date: 19 December 1996 (19.12.96)
(21) International Application Number: PCT/US96/08613 (22) International Filing Date: 6 June 1996 (06.06.96) (30) Priority Data: 08/484,928 7 June 1995 (07.06.95) US (71)(72) Applicant and Inventor: MICHELSON, Gary, K. [US/US]; 438 Sherman Canal, Venice, CA 90291 (US). (74) Agent: SCHELLIN, Eric, P.; Suite 704, 2121 Crystal Drive, Arlington, VA 22202 (US).			(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
			<b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS



(57) Abstract

The present invention is directed to a variety of interbody spinal fusion implants (220, 320 and 420) having at least a partially frusto-conical configuration. The spinal fusion implants (220, 320 and 420) of the present invention may be relatively solid or hollow and may have surface roughenings to promote bone ingrowth and stability. The spinal fusion implants (220, 320 and 420) of the present invention may have wells (260) extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. A variety of surface irregularities may be employed to increase implant stability and implant surface area, and/or for the purpose of advancing the spinal fusion implant into the fusion site.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

## FRUSTO-CONICAL INTERBODY

## SPINAL FUSION IMPLANTS

BACKGROUND OF THE INVENTIONRelated Applications

5           This application is a continuation in part of  
compending United States application Serial No. 08/396,414  
filed on February 27, 1995 which is a continuation-in-part  
of United States application Serial No. 08/074,781 filed on  
June 10, 1993, which is a continuation in part of United  
0       States application Serial No. 07/698,674 filed on May 10,  
1991 which is a divisional of application Serial No.  
07/205,935 filed on June 13, 1988, now United States Patent  
No. 5,015,247, all of which are incorporated herein by  
reference.

15           This application is also a continuation-in-part  
of United States application Serial No. 08/390,131 entitled  
| Interbody Spinal Fusion Implants filed on February 17,  
1995.

Field of the Invention

20           The present invention relates generally to  
interbody spinal fusion implants, and in particular to  
spinal fusion implants configured to restore and maintain  
two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

25           Interbody spinal fusion refers to the method of  
achieving bony bridging between adjacent vertebrae through  
the disc space, the space between adjacent vertebrae  
normally occupied by a spinal disc. Numerous implants to  
facilitate such a fusion have been described by Cloward,  
30       Brantigan, and others, and are known to those skilled in  
the art. Generally, cylindrical implants offer the

advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Therefore, there exists a need for spinal fusion implants that permit for the restoration of anatomical lordosis.

#### SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration to achieve a desired anatomical lordosis of the spine. In the preferred embodiment, the spinal fusion implants of the present invention have an outer locus in which at least some of the points of the implant comprise a partially or fully frusto-conical shape substantially along those portions of the implant in contact with the adjacent vertebrae of the spine and have an insertion end and a trailing end. The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a frusto-cone, at least one side portion may be truncated to form a planar surface that is parallel to the central longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the insertion end of the implant to facilitate insertion. The spinal fusion implants of the present invention may be

relatively solid and/or porous and/or hollow, and may have surface roughenings to promote bone ingrowth and stability.

The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes, may pass either into or through the implant and may or may not intersect. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant.

Said chamber may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means. Still further, a variety of surface irregularities may be employed to increase implant stability and implant surface area, and/or for the purpose of allowing the spinal fusion implant to be inserted easily but to resist motion in the opposition direction. The exterior of the spinal fusion implant of the present invention may have wholly or in part, a rough finish, knurling, forward facing ratchetings or other surface irregularities sufficient to achieve the purpose described.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape, those that taper from the leading edge to the trailing edge are easy to introduce and easy to fully insert into the spinal segment to be fused.

2. The shape of the implants of the present invention is consistent with the shape of the disc, which the implants at least in part replace, wherein the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics or combination sufficient for the intended purpose. Further, the spinal fusion implants of the present invention may be made of a solid material, a mesh-like material, a porous material and/or may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be loaded with, composed of, treated or coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, to make them bioactive for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.



OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

5 It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

10 It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

15 It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

20 It is still another object of the present invention to provide a spinal fusion implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

25 It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

30 It is still further another object of the present invention to provide a spinal fusion implant that is consistent in use with the preservation of a uniform

thickness of the subchondral vertebral bone;

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to an easily produced complementary bore at the fusion site; and

It is a further object of the present invention to provide a frusto-conical spinal fusion implant which may be placed side by side adjacent to a second identical implant across the same disc space, such that the combined width of the two implants is less than sum of the individual heights of each implant.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of an embodiment of the spinal fusion implant of the present invention having a frusto-conical body and a surface configuration comprising ratchetings for engaging bone, with wells and channels for bone ingrowth.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 2 is a cross sectional view along line 2--2 of the implant of Figure 1 illustrating the channels and wells of the implant of the present invention.

Figure 3 is a cross sectional view along line 3--3 of the implant of Figure 1 illustrating the channels and wells of the implant of the present invention.

Figure 3A is a side elevational view of an alternative embodiment of the spinal fusion implant of the

present invention having a frusto-conical body and a plurality of ratchetings forming a cylindrical external configuration.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having truncated sides forming a planar surface parallel to the longitudinal axis of the implant and ratchetings having a radius and height that are not constant.

Figure 5 is a top plan view of the spinal fusion implant shown in Figure 4.

Figure 6 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous mesh-like material that is partially frusto-conical with one side that is truncated shown next to an identical second implant illustrated in hidden line.

Figure 7 is sectional view along line 7--7 of the implants of Figure 6.

Figure 8 is an enlarged fragmentary view along line 8 of Figure 6 illustrating the surface configuration of the implant of Figure 6.

Figure 9 is an enlarged fragmentary view along line 8 of Figure 6 illustrating an alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 10 is a cross sectional view along lines 10--10 of Figure 9 illustrating the alternative embodiment of the surface configuration of the implant of the present invention made of a cancellous material.

Figure 11 is a side elevational view in partial

cut-away of an alternative embodiment of the spinal fusion implant of the present invention having a body that is frusto-conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 12 is an enlarged fragmentary sectional view along lines 12--12 of Figure 11 illustrating the surface configuration of the implant of Figure 11.

#### DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, an embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a frusto-conical body 222 and an outer locus that is generally frusto-conical substantially along the portion of the implant 220 that is in contact with the adjacent vertebrae of the spine. The implant 220 has a surface configuration of forward facing ratchetings 240 suitable for engaging the bone of the adjacent vertebrae. Each of the plurality of ratchetings 240 has a bone engaging edge 242 and ramped portion 244. The ratchetings 240 have a radius  $R_1$  measured from the central longitudinal axis  $L_1$  of the implant 220 that increases from the insertion end 224 to the trailing end 226. The height of the ratchetings 240 measured from the body 222 is constant throughout the length of implant 220.

The orientation of the ratchetings 240 makes the insertion of the implant 220 easier than its removal, as the ramped portions 244 act as an inclined plane on the way in, while the bone engaging edges 242 resist motion in the opposite directions. These forward facing ratchetings 240 tend to urge the implant 220 forward until the unremoved bone of the vertebrae blocks further motion resulting in a

very stable spine and implant construct.

The implant 220 has a recessed slot 234 at its trailing end 226 for receiving and engaging insertion instrumentation for inserting the implant 220. The recessed slot 234 has a threaded opening 236 for threadably attaching the implant 220 to instrumentation used for inserting the implant 220.

In the preferred embodiment, the bone engaging edges 242 of the ratchetings 240 have a height at a highest point measured from the body 222 (root diameter) of the implant 220 in the range of 0.25 - 2.0 mm, with the preferred height being 0.4 mm for use in the cervical spine and 1.25 mm for use in the lumbar spine.

Referring to Figures 2 and 3, cross sectional views of implant 220 are shown. The implant 220 has channels 250 passing through the implant 220 and wells 260 formed in the surface of the implant 220. The wells 260 may or may not communicate with the channels 250. In the preferred embodiment of implant 220, the channels 250 have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The wells 260 have a diameter in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels 250 and wells 260 are shown having a generally rounded configuration, it is within the scope of the present invention that the channels 250 and wells 260 may have any size, shape, configuration, and distribution suitable for the intended purpose.

Referring to Figure 1A, the implant 220 has an outer surface 238 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer

surface 238 is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. It is appreciated that the outer surface 238, and/or the entire implant 220, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant 220 may be further coated with bioactive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 220 is shown as being solid, however it is appreciated that it can be made to be substantially hollow or hollow in part.

While the implant 220 is shown as being solid, it is appreciated that the implant 220 can be hollow at least in part to provide an internal chamber for holding bone or any fusion promoting material. Such an implant could have openings to allow bone external to the implant to grow into the internal chamber. Such structure is disclosed in detail in co-pending application serial no. 08/390,131 and co-pending application serial no. 08/074,781, both of which are incorporated herein by reference.

Referring to Figure 3A, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220'. The implant 220' is similar in configuration to implant 220 except that the body 222' of the implant is frusto-conical in configuration and the ratchetings 240' have a radius  $R_3$  measured from the longitudinal central axis  $L_4$  that is constant in size from the insertion end 224' to the trailing end 226'. The

ratchetings 240' each have a height measured from the body 222' that is not constant throughout the length of the implant 220' and decreases from the insertion end 224' to the trailing end 226'. In this manner, the ratchetings 240' form an external configuration of the implant 220' that is substantially cylindrical in shape, while the body 220' is frusto-conical. The insertion end of implant 220' may have a tapered portion 223' of lesser diameter to facilitate insertion of the implant 220'.

Referring to Figures 4 and 5, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220''. The implant 220'' is similar in configuration to implant 220 and has ratchetings 240'' having a radius  $R_s$  measured from the longitudinal central axis  $L_s$  that increases in size from the insertion end 224'' to the trailing end 226''. The ratchetings 240' each have a height measured from the body 222'' that is not constant throughout the length of the implant 220''. In the preferred embodiment, the ratchet radius  $R_s$  and the ratchet height increase in size from the insertion end 224'' to the trailing end 226''.

As shown in Figure 5, the implant 220' has truncated sides 270 and 272 forming two planar surfaces which are diametrically opposite and are parallel to the longitudinal axis  $L_4$ . In this manner, two implants 220' may be placed side by side with one of the sides 270 or 272 of each implant touching, such that the area of contact with the bone of the adjacent vertebrae and the ratchetings 240' is maximized. Alternatively, the implant 220' may have one truncated side.

Referring to Figures 6-8, an alternative

embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 320a. The implant 320a is shown placed next to a second identical implant 320b shown in hidden line. The implant 320a has a body 322 that is made of a mesh-like material comprising strands, which may be made of metal, that are pressed together and molded into a partially frusto-conical configuration substantially along the portion of the implant 320a in contact with the adjacent vertebrae of the spine. The implant 320a has an insertion end 324 and a trailing end 326 and may be made wholly or in part of a solid material and/or a porous material, and/or a mesh-like material. The implant 320a may have a surface comprising of a porous material, a mesh-like material, or have a surface that is roughened. It is appreciated that the implant 320a may be solid or may be partially hollow and include at least one internal chamber. As shown in Figure 8, the mesh-like material comprises strands that are formed and pressed together such that interstices 339, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 338 of implant 320a.

Referring to Figures 9 and 10, alternatively the implant 320a may be made of a cancellous material 350, similar in configuration to human cancellous bone, having interstices 352 such that the outer surface 338 has a configuration as shown in Figures 9 and 10. As the implant 320a may be made entirely or in part of the cancellous material 350, the interstices 352 may be present in the outer surface 338 and/or within the entire implant 320a to promote bone ingrowth and hold bone fusion promoting



materials.

Referring again to Figure 7, the implant 320a is partially frusto-conical, similar in shape to implant 20 but having at least one truncated side 340 that forms a planar surface parallel to the central longitudinal axis of implant 320. The truncated side 340 allows for the placement of two implants 320a and 320b closer together when placed side by side between two adjacent vertebrae as set forth in U.S. Patent Application Serial No. 08/390,131, incorporated herein by reference. Implant 320a may be partially threaded or may otherwise resemble any of the other embodiments herein described or that are functionally equivalent.

Referring to Figure 11, a side elevational view in partial cut-away of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 420. The implant 420 has a body 422 that is frusto-conical in shape substantially along the portion of the implant 420 that is in contact with the adjacent vertebrae of the spine and has an insertion end 424 and a trailing end 426. The implant 420 has an outer surface 438 that is capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the surface 438 comprises a plurality of posts 440 that are spaced apart to provide a plurality of interstices 442 which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by grouting or otherwise coating the surface 438 with the appropriate

fusion promoting substances.

Referring to Figure 12, an enlarged view of the surface 438 of implant 420 is shown. In the preferred embodiment, the posts 440 have a head portion 444 of a larger diameter than the remainder of the posts 440, and each of the interstices 442 is the reverse configuration of the posts 444, having a bottom 446 that is wider than the entrance 448 to the interstices 442. Such a configuration of the posts 440 and interstices 442 aids in the retention of bone material in the surface 438 of the implant 420 and further assists in the locking of the implant 420 into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom 466 of the interstices 442 is wider than the entrance 448, the bone ingrowth cannot exit from the entrance 448 and is locked within the interstice 442. The surface 438 of the implant 420 provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts 440 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 442 have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is

15 -

appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

5

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

What is claimed is:

1. A frusto-conical interbody spinal fusion implant, comprising:

a body having an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine, the outer locus of said bone engaging means forming a substantially frusto-conical configuration, said implant being made of a material appropriate for human implantation.

2. The implant of claim 1 in which said body has a substantially frusto-conical configuration.

3. The implant of claim 1 in which said body has a substantially cylindrical configuration.

4. The spinal fusion implant of claim 1 in which said trailing end is larger than said insertion end.

5. The spinal fusion implant of claim 1 in which said insertion end is larger than said trailing end.

6. The spinal fusion implant of claim 1 in which said implant comprises a bone ingrowth material.

7. The spinal fusion implant of claim 1 in which said implant comprises a fusion promoting material.

8. The spinal fusion implant of claim 1 in which said implant is at least in part bioabsorbable.

9. The spinal fusion implant of claim 1 having a plurality of openings capable retaining fusion promoting material.

10. The spinal fusion implant of claim 1 in which said bone engaging means comprises said outer surface being porous at least in part.

11. The spinal fusion implant of claim 1 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

5 12. The spinal fusion implant of claim 11 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

10 13. The spinal fusion implant of claim 1 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

15 14. The spinal fusion implant of claim 1 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

16 15. The spinal fusion implant of claim 14 in which said surface roughenings include a plurality of ratchetings.

17 16. The spinal fusion implant of claim 14 in which said surface roughenings include knurling.

25 17. The spinal fusion implant of claim 1 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

18. The spinal fusion implant of claim 17 in which said internal chamber is capable of containing fusion promoting material.

30 19. The spinal fusion implant of claim 17 in which said implant comprises a wall surrounding said internal

chamber.

20. The spinal fusion implant of claim 17 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

5 21. The spinal fusion implant of claim 17 in which said implant has means for closing said access opening.

22. The spinal fusion implant of claim 1 in which said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

10 23. The spinal fusion implant of claim 1 in which at least a portion of said outer surface comprises wells having at least partial walls.

15 24. The spinal fusion implant of claim 1 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

25 25. The spinal fusion implant of claim 1 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

26. A frusto-conical interbody spinal fusion implant, comprising:

25 a body having an insertion end, a trailing end and an outer surface; and

30 bone engaging means for engaging said implant to adjacent vertebrae of the spine, the locus of said bone engaging means forming a substantially cylindrical configuration, said implant being made of a material appropriate for human implantation.

27. The implant of claim 26 in which said body has a substantially frusto-conical configuration.

28. The implant of claim 26 in which said body has at least in part a cylindrical configuration.

5 29. The spinal fusion implant of claim 26 in which said trailing end is larger than said insertion end.

30. The spinal fusion implant of claim 26 in which said insertion end is larger than said trailing end.

10 31. The spinal fusion implant of claim 26 in which said implant comprises a bone ingrowth material.

32. The spinal fusion implant of claim 26 in which said implant comprises a fusion promoting material.

33. The spinal fusion implant of claim 26 in which said implant is at least in part bioabsorbable.

15 34. The spinal fusion implant of claim 26 having a plurality of openings capable retaining fusion promoting material.

35. The spinal fusion implant of claim 26 in which said bone engaging means comprises said outer surface being porous at least in part.

36. The spinal fusion implant of claim 26 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

25 37. The spinal fusion implant of claim 36 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

30 38. The spinal fusion implant of claim 26 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion

promoting material.

39. The spinal fusion implant of claim 26 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

40. The spinal fusion implant of claim 39 in which said surface roughenings include a plurality of ratchetings.

41. The spinal fusion implant of claim 39 in which said surface roughenings include knurling.

42. The spinal fusion implant of claim 26 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

43. The spinal fusion implant of claim 42 in which said internal chamber is capable of containing fusion promoting material.

44. The spinal fusion implant of claim 42 in which said implant comprises a wall surrounding said internal chamber.

45. The spinal fusion implant of claim 42 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

47. The spinal fusion implant of claim 42 in which said implant has means for closing said access opening.

48. The spinal fusion implant of claim 26 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

49. The spinal fusion implant of claim 26 in which at



least a portion of said outer surface comprises wells having at least partial walls.

50. The spinal fusion implant of claim 26 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

51. The spinal fusion implant of claim 26 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

52. The spinal fusion implant of claim 51 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

53. A frusto-conical interbody spinal fusion implant, comprising:

a body having a substantially frusto-conical configuration, an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine, the outer locus of said bone engaging means forming a substantially frusto-conical configuration, said implant being made of a material appropriate for human implantation.

54. The spinal fusion implant of claim 53 in which said trailing end is larger than said insertion end.

55. The spinal fusion implant of claim 53 in which said insertion end is larger than said trailing end.

56. The spinal fusion implant of claim 53 in which said implant comprises a bone ingrowth material.

57. The spinal fusion implant of claim 53 in which said implant comprises a fusion promoting material.

58. The spinal fusion implant of claim 53 in which said implant is at least in part bioabsorbable.

59. The spinal fusion implant of claim 53 having a plurality of openings capable retaining fusion promoting material.

60. The spinal fusion implant of claim 53 in which said bone engaging means comprises said outer surface being porous at least in part.

61. The spinal fusion implant of claim 53 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

62. The spinal fusion implant of claim 61 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

63. The spinal fusion implant of claim 53 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

64. The spinal fusion implant of claim 53 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

65. The spinal fusion implant of claim 64 in which said surface roughenings include a plurality of ratchetings.

66. The spinal fusion implant of claim 64 in which said surface roughenings include knurling.

67. The spinal fusion implant of claim 53 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

68. The spinal fusion implant of claim 67 in which said internal chamber is capable of containing fusion promoting material.

69. The spinal fusion implant of claim 67 in which said implant comprises a wall surrounding said internal chamber.

70. The spinal fusion implant of claim 67 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

71. The spinal fusion implant of claim 67 in which said implant has means for closing said access opening.

72. The spinal fusion implant of claim 53 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

73. The spinal fusion implant of claim 53 in which at least a portion of said outer surface comprises wells having at least partial walls.

74. The spinal fusion implant of claim 53 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said first and second implants.

75. The spinal fusion implant of claim 53 having a

longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

76. The spinal fusion implant of claim 75 in which said external thread has a thread height measured from said body which is greatest at said truncated side.

77. An interbody spinal fusion implant, comprising:  
a body having a substantially cylindrical configuration, an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine, the locus of said bone engaging means forming a substantially cylindrical configuration, said implant being made of a material appropriate for human implantation.

78. The spinal fusion implant of claim 77 in which said implant comprises a bone ingrowth material.

79. The spinal fusion implant of claim 77 in which said implant comprises a fusion promoting material.

80. The spinal fusion implant of claim 77 in which said implant is at least in part bioabsorbable.

81. The spinal fusion implant of claim 77 having a plurality of openings capable retaining fusion promoting material.

82. The spinal fusion implant of claim 78 in which said bone engaging means comprises said outer surface being porous at least in part.

83. The spinal fusion implant of claim 78 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

25 .

84. The spinal fusion implant of claim 83 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

5 85. The spinal fusion implant of claim 78 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

10 86. The spinal fusion implant of claim 78 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

15 87. The spinal fusion implant of claim 86 in which said surface roughenings include a plurality of ratchetings.

88. The spinal fusion implant of claim 86 in which said surface roughenings include knurling.

20 89. The spinal fusion implant of claim 78 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

25 90. The spinal fusion implant of claim 89 in which said internal chamber is capable of containing fusion promoting material.

91. The spinal fusion implant of claim 89 in which said implant comprises a wall surrounding said internal chamber.

30 92. The spinal fusion implant of claim 89 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

93. The spinal fusion implant of claim 89 in which said implant has means for closing said access opening.

5 94. The spinal fusion implant of claim 78 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

95. The spinal fusion implant of claim 78 in which at least a portion of said outer surface comprises wells having at least partial walls.

10 96. The spinal fusion implant of claim 78 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than  
15 the sum of the individual maximum diameters of each of said first and second implants.

97. The spinal fusion implant of claim 78 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

9 98. A frusto-conical interbody spinal fusion implant, comprising:

a body having a substantially frusto-conical configuration, an insertion end, a trailing end and an outer surface; and

25 bone engaging means for engaging said implant to adjacent vertebrae of the spine, said implant being made of a material appropriate for human implantation.

99. The implant of claim 98 in which the outer locus of said bone engaging means forms a substantially frusto-conical configuration.  
30

100. The implant of claim 98 in which said the outer locus of said bone engaging means forms a substantially cylindrical configuration.

5 101. The spinal fusion implant of claim 98 in which said insertion end is larger than said trailing end.

102. The spinal fusion implant of claim 101 in which said insertion end comprises a tapered leading portion.

103. The spinal fusion implant of claim 98 in which said trailing end is larger than said insertion end.

10 104. The spinal fusion implant of claim 98 in which said implant comprises a bone ingrowth material.

105. The spinal fusion implant of claim 98 in which said implant comprises a fusion promoting material.

15 106. The spinal fusion implant of claim 98 in which said implant is at least in part bioabsorbable.

107. The spinal fusion implant of claim 98 having a plurality of openings capable retaining fusion promoting material.

108. The spinal fusion implant of claim 98 in which said bone engaging means comprises said outer surface being porous at least in part.

25 109. The spinal fusion implant of claim 98 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

110. The spinal fusion implant of claim 109 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

30 111. The spinal fusion implant of claim 98 in which said bone engaging means comprises a mesh-like material

having a plurality of interstices for receiving fusion promoting material.

112. The spinal fusion implant of claim 98 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

113. The spinal fusion implant of claim 112 in which said surface roughenings include a plurality of ratchetings.

114. The spinal fusion implant of claim 112 in which said surface roughenings include knurling.

115. The spinal fusion implant of claim 98 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

116. The spinal fusion implant of claim 115 in which said internal chamber is capable of containing fusion promoting material.

117. The spinal fusion implant of claim 115 in which said implant comprises a wall surrounding said internal chamber.

118. The spinal fusion implant of claim 115 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

119. The spinal fusion implant of claim 115 in which said implant has means for closing said access opening.

120. The spinal fusion implant of claim 98 in which one of said ends of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.



121. The spinal fusion implant of claim 98 in which at least a portion of said outer surface comprises wells having at least partial walls.

5 122. The spinal fusion implant of claim 98 in which said implant is configured to be placed in close proximity in a side by side alignment to a second spinal fusion implant, said first and second implants when placed together having a combined overall width that is less than the sum of the individual maximum diameters of each of said  
10 first and second implants.

123. The spinal fusion implant of claim 98 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

15 124. A frusto-conical interbody spinal fusion implant, comprising:

a body having an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine, the outer locus of said  
20 bone engaging means forming a substantially frusto-conical configuration substantially along a portion of said bone engaging means in contact with said adjacent vertebrae, said implant being made of a material appropriate for human implantation.

25 125. The implant of claim 124 in which said body has a substantially frusto-conical configuration substantially along a portion of said outer surface in contact with said adjacent vertebrae.

30 126. The implant of claim 124 in which said body has a substantially cylindrical configuration substantially along a portion of said outer surface in contact with said

adjacent vertebrae.

127. The spinal fusion implant of claim 124 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

128. The spinal fusion implant of claim 124 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

129. The spinal fusion implant of claim 124 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

130. The spinal fusion implant of claim 124 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

131. A spinal fusion implant, comprising:

a body having an outer locus larger than the space between two adjacent vertebrae to be fused, said outer locus being substantially cylindrical along a portion of said implant in contact with said adjacent vertebrae; and bone engaging means for engaging said implant to said adjacent vertebrae of the spine on the exterior of said body, said implant being made of a material appropriate for human implantation.

132. The spinal fusion implant of claim 131 including a plurality of openings in the exterior surface of said implant.

133. The spinal fusion implant of claim 131 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

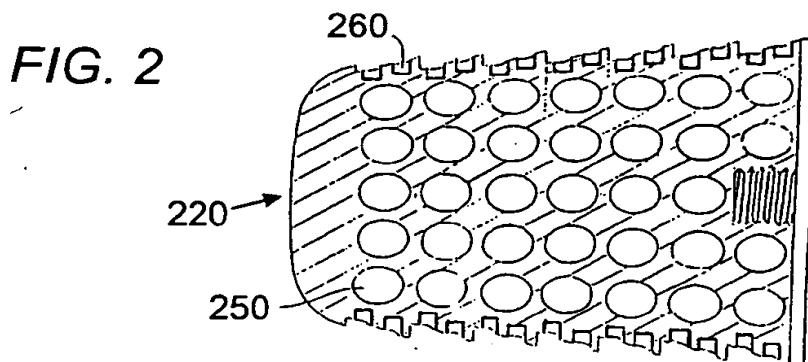
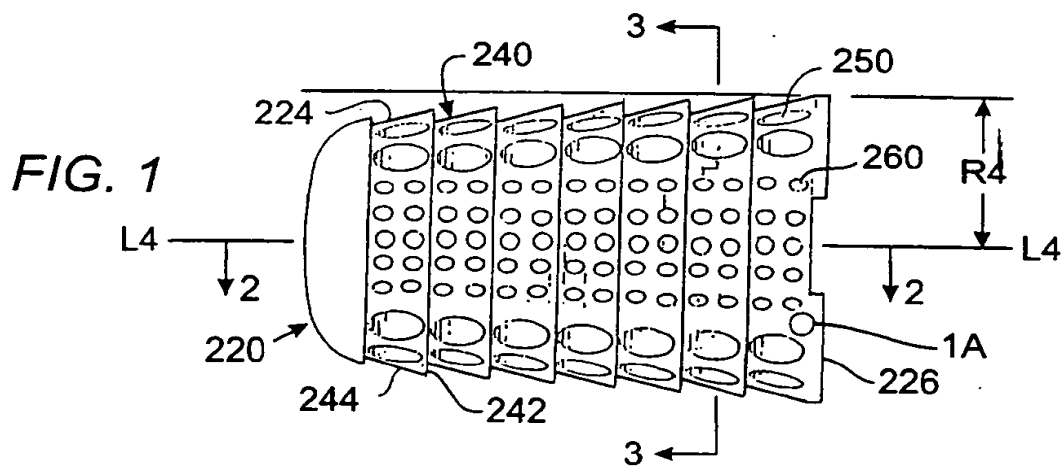
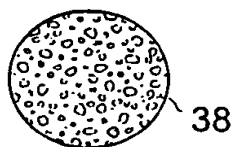
5 134. The spinal fusion implant of claim 131 in which said bone engaging means comprises a mesh-like material having a plurality of interstices for receiving fusion promoting material.

10 135. The spinal fusion implant of claim 131 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of said outer surface of said implant.

15 136. The spinal fusion implant of claim 131 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

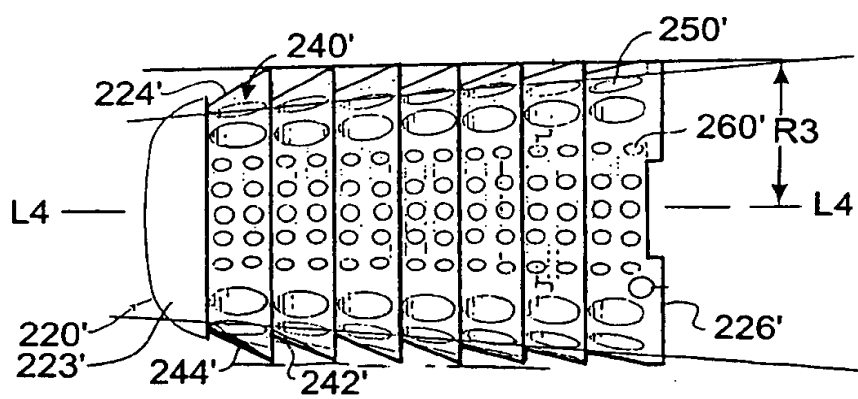
1 / 5

FIG. 1A

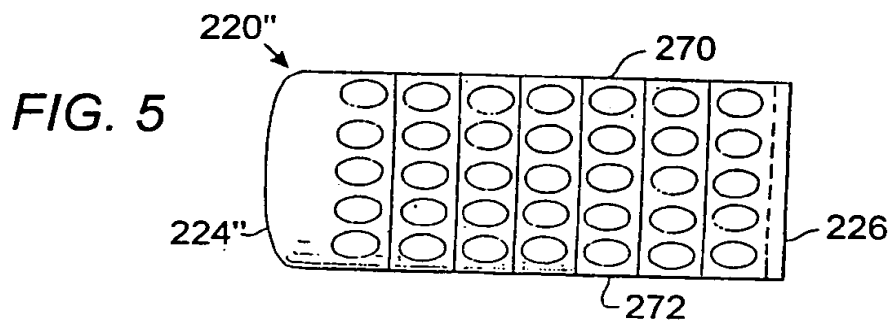
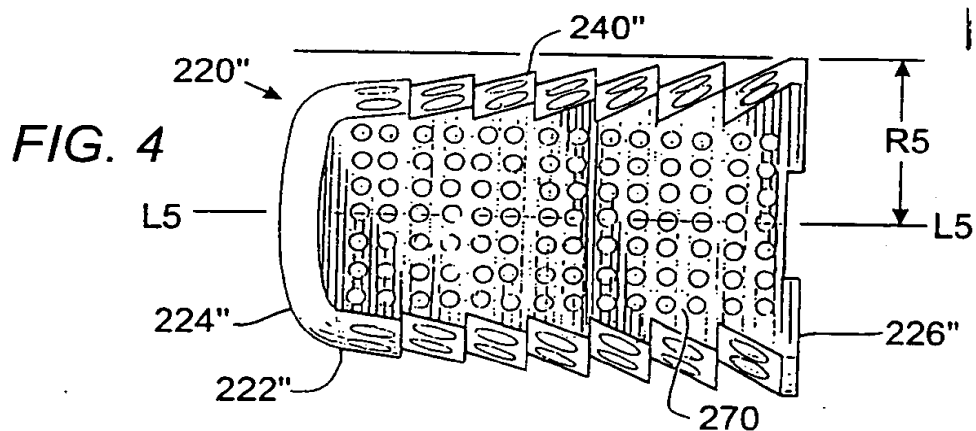
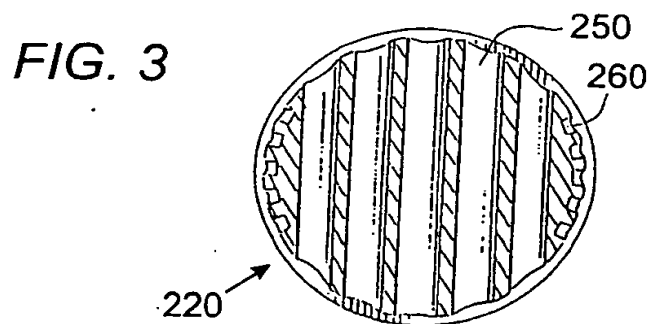


SUBSTITUTE SHEET (RULE 26)

FIG. 3A



3 / 5



**SUBSTITUTE SHEET (RULE 26)**

4 / 5

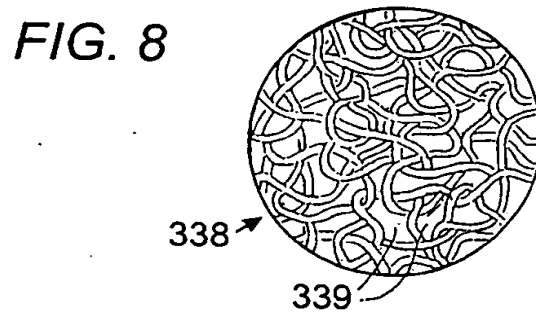
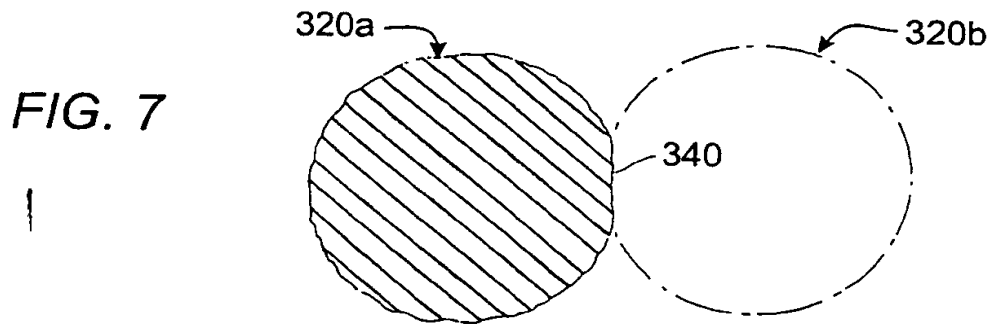
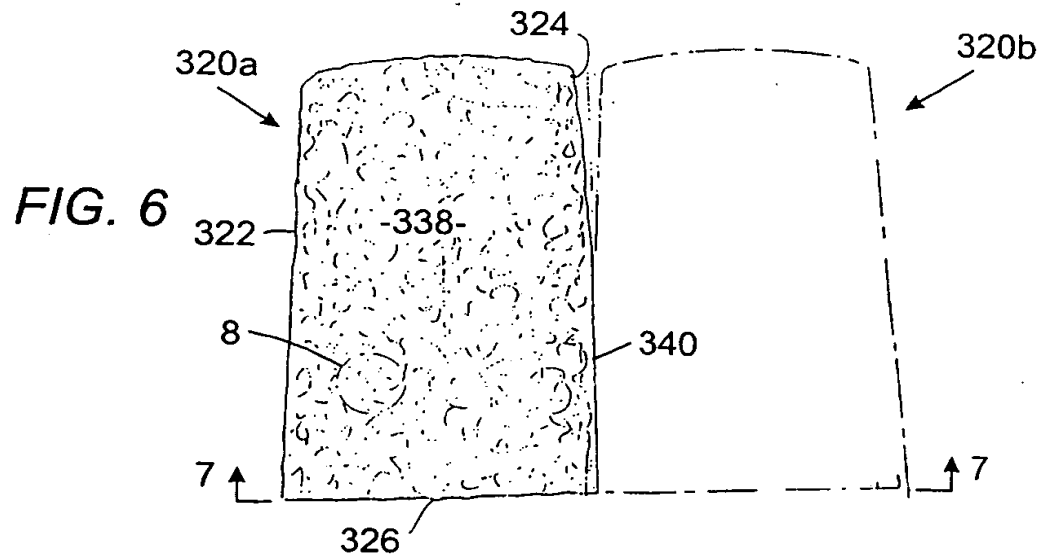


FIG. 9

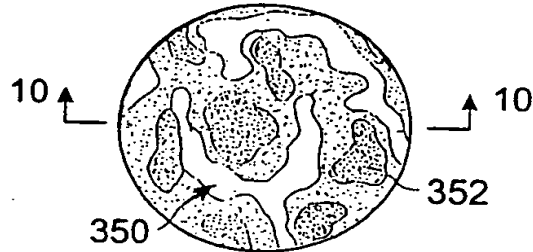


FIG. 10

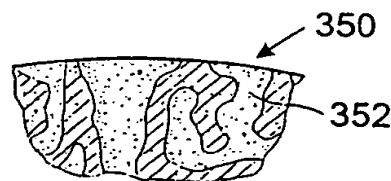


FIG. 11

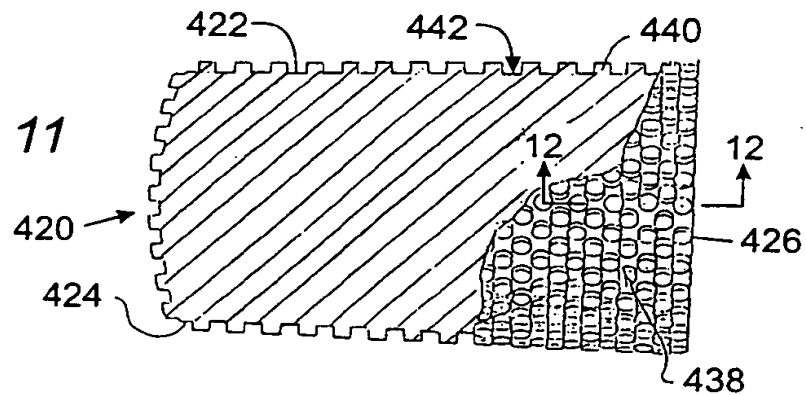
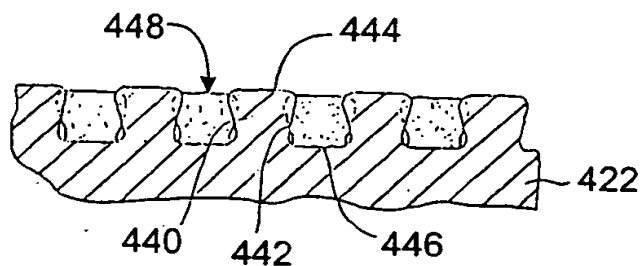


FIG. 12



SUBSTITUTE SHEET (RULE 26)



# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/08613

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 5/04  
US CL : 606/61; 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 72-79; 623/16, 17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
APS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,349,921 (KUNTZ) 21 September 1982, see Figs. 15, and column 13 lines 34-42.	1-4, 22, 26-29, 48, 53, 54, 73, 77, 94, 98-103, 120, 134-126, 131 ----- 5-7, 9, 10, 17-20, 30-32, 34, 35, 42-45, 55-57, 59, 60, 67-70, 78-82, 89-92, 104, 105, 107, 108 115-118, 132

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Special categories of cited documents:	
*A* document defining the general state of the art which is not considered to be of particular relevance	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*E* earlier document published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*O* document referring to an oral disclosure, use, exhibition or other means	*Z* document member of the same patent family
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search  
12 AUGUST 1996

Date of mailing of the international search report  
31 OCT 1996

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20530

Authorized officer

*Hania Sineik*  
MICHAEL A. BROWN

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/08613

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,936,848 (BAGBY) 26 June 1990, see the entire document.	1-136
Y	US, A, 4,904,260 (RAY ET AL.) 27 February 1990, see the entire document.	8, 13, 33, 38, 58, 63, 80, 85, 106, 111, 128, 134
Y	US, A, 4,878,915 (BRANTIGAN) 07 November 1989, see the entire document.	11, 14-16, 23, 24, 36, 39-41, 49, 50, 61, 64- 66, 73, 74, 83, 84, 86-88, 95, 96, 109, 112- 114, 121, 122, 127, 129, 133, 135
Y	US, A, 4,961,740 (RAY ET AL.) 09 October 1990, see the entire document.	21, 47, 71, 93, 119

Form PCT/ISA/210 (continuation of second sheet)(July 1992)\*

1 / 5

FIG. 1A

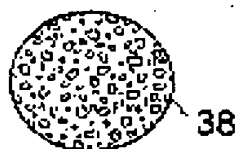


FIG. 1

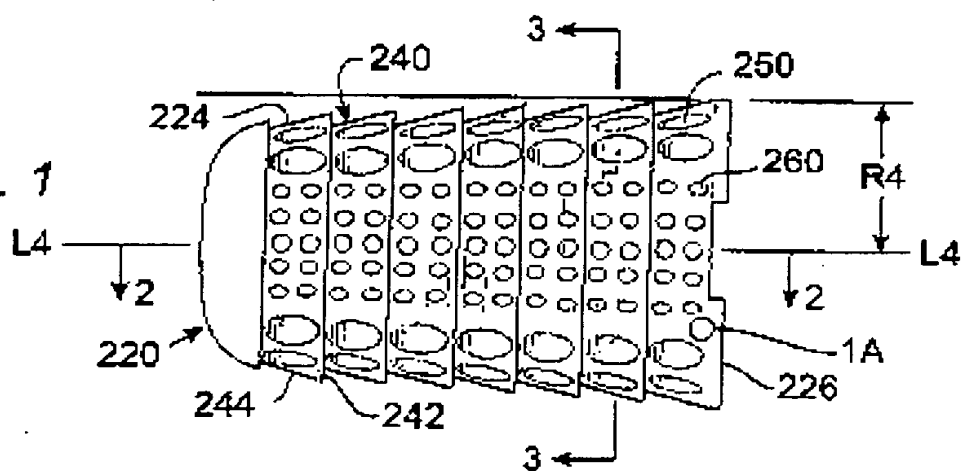
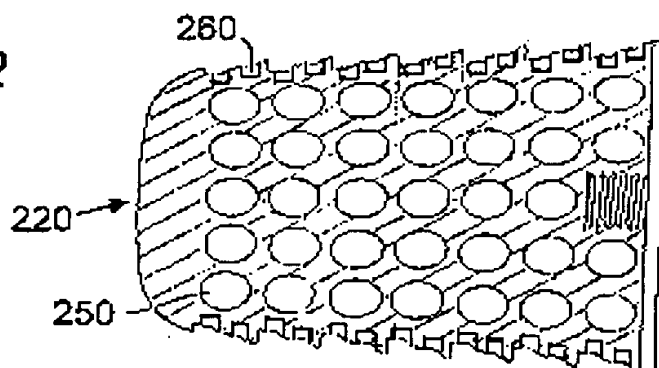
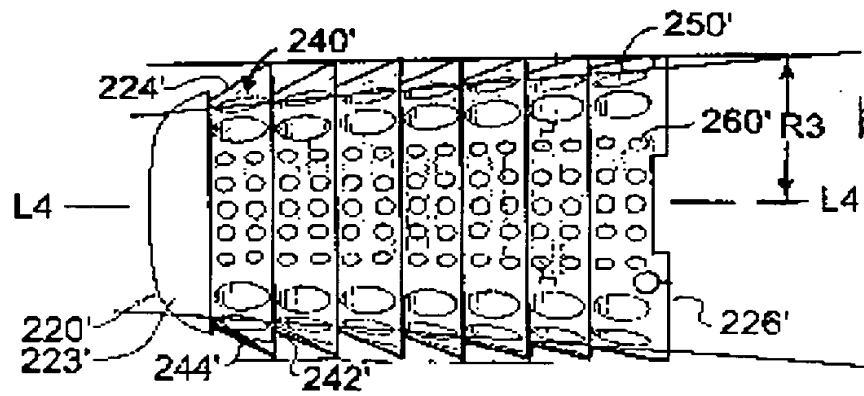


FIG. 2



215

FIG. 3A



SUBSTITUTE SHEET (RULE 26)

3 / 5

FIG. 3

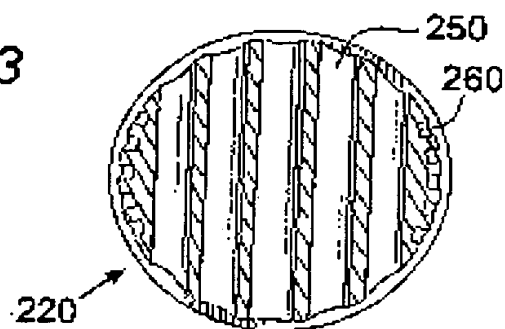


FIG. 4

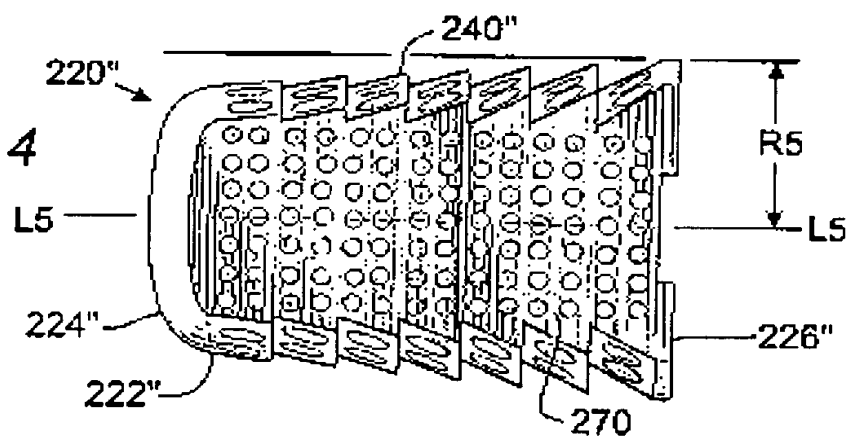
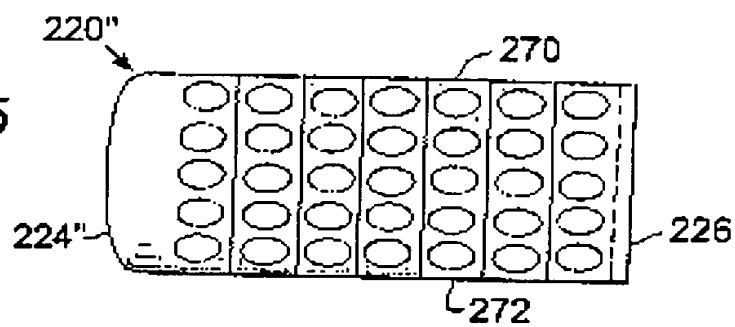
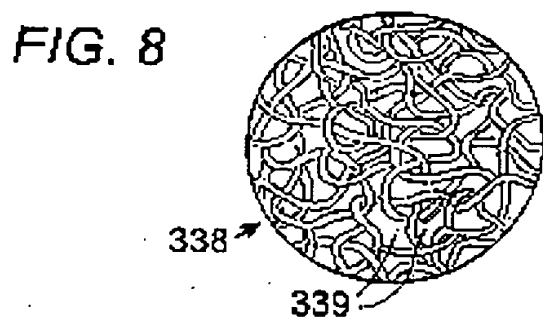
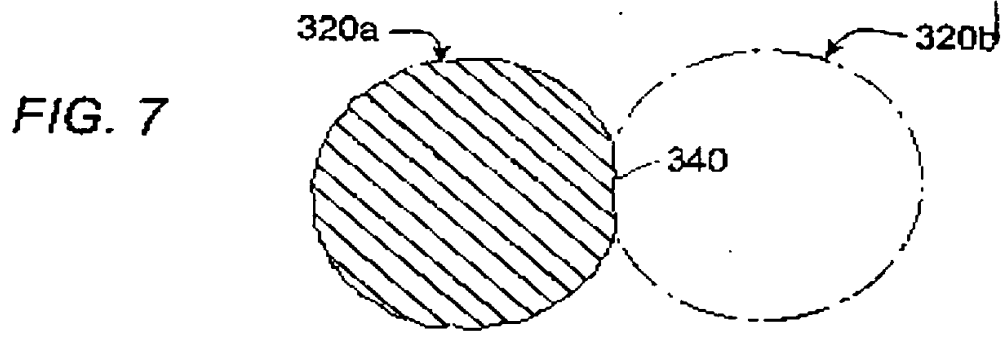
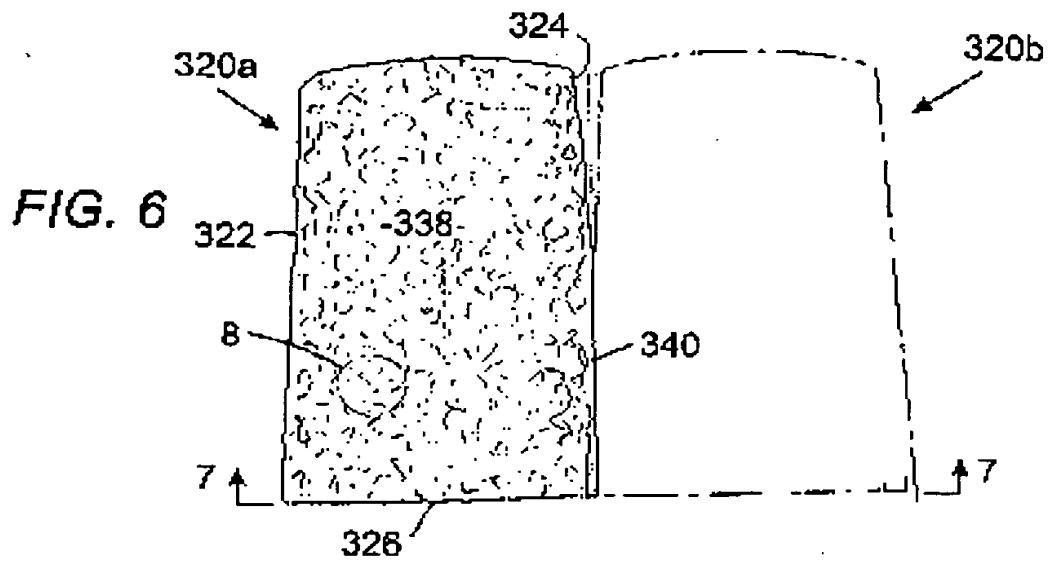


FIG. 5



4 / 5



SUBSTITUTE SHEET (RULE 26)

5/5

FIG. 9



FIG. 10

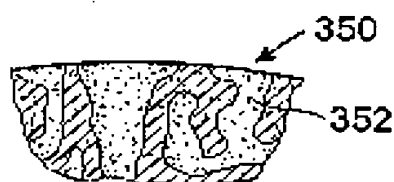


FIG. 11

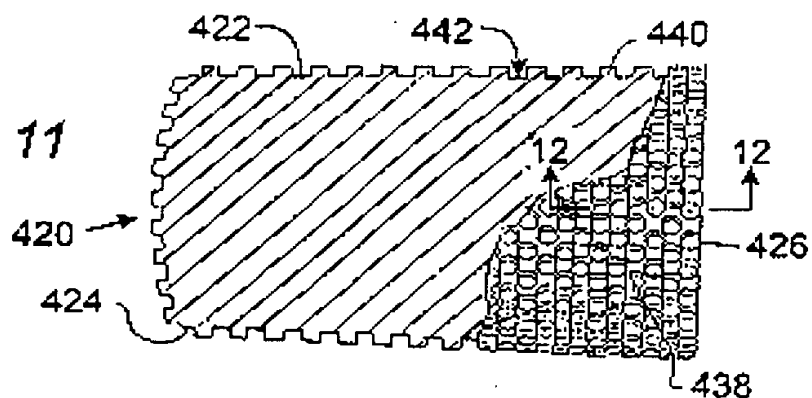
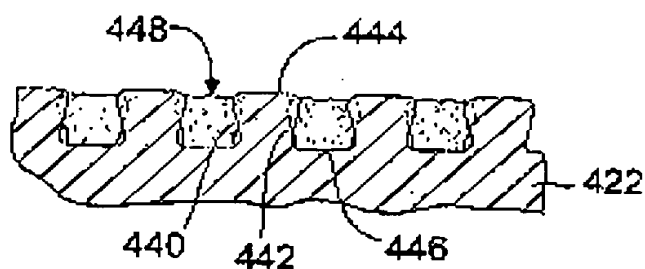


FIG. 12



**THIS PAGE BLANK (USPTO)**